Complete Summary

GUIDELINE TITLE

Report on the management of staghorn calculi.

BIBLIOGRAPHIC SOURCE(S)

American Urological Association Education and Research, Inc.. Report on the management of staghorn calculi. Linthicum (MD): American Urological Association Education and Research, Inc.; 2005. Various p. [81 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Staghorn calculi (partial and complete)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics

Surgery
Urology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for the diagnosis and treatment of staghorn calculi

TARGET POPULATION

Adult and pediatric patients with partial or complete staghorn calculi

INTERVENTIONS AND PRACTICES CONSIDERED

1. Percutaneous nephrolithotomy (PNL) monotherapy
2. Combinations of percutaneous nephrolithotomy and shock-wave lithotripsy (SWL)
3. Shock-wave lithotripsy monotherapy
4. Open surgery
5. Nephrectomy

MAJOR OUTCOMES CONSIDERED

- Percentage of patients who become stone free (stone-free rate)
- Mean number of primary, secondary, and adjunctive procedures that patients undergo
- Frequency of patients having acute complications associated with the chosen primary treatment modality (complication rate)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The initial literature database used for the analysis was developed using MEDLINE® and MeSH® headings related to staghorn calculi. The database spanned the period from July 1992 through July 2003 (subsequent to the time period reflected in the 1994 clinical practice guideline) and was limited to human studies published in the English language.

Ninety-six citations were chosen on the basis of key words and recommendations by Panel members. The Panel considered 58 articles to be candidates for data extraction. These 58 articles were divided among the six Panel members, and data were extracted using an updated version of the extraction instrument that

was used to develop the 1994 guideline. Most (43 of 58) articles were extracted by a single Panel member, but 26% (15 of 58) of the articles were extracted independently by two Panel members who then reconciled their findings. Double extraction was performed either when an article was in the top quartile with regard to numbers of patients reported or when a Panel member requested a second extraction due to complexity of the data. Thirty-two articles ultimately were included in the final database. Reasons for excluding articles from further analysis were as follows:

1. The article was included in the previous 1994 guideline.
2. The article did not provide data on the outcomes of interest.
3. Results for patients where staghorn stones could not be separated from results for those with non-staghorn stones. In a few cases, articles were included that reported primarily on patients with staghorns but that also reported on a few patients with large stones that could not be verified as staghorns.
4. The treatments used were not current or were not the focus of the analysis
5. The article reported data for fewer than five relevant patients (n=3).
6. The article dealt solely with cystine stones (n=2)

The data extraction form and a complete list of included references are available in Appendix 2 in the original guideline document.

NUMBER OF SOURCE DOCUMENTS

32

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Stone-free and acute complication data were evaluated using meta-analyses with the confidence profile method developed by Eddy and associates that allows data from studies that are not randomized, controlled trials to be analyzed. A complete description of the data analysis is included in Chapter 2 of the full guideline report. Herein, results of meta-analyses are reported as medians expressed as percentages. These values provide the best estimate of a patient's probability of experiencing the event (being stone free or having an acute complication). The

probability (Bayesian) is 5% that the true value is outside the associated 95% confidence interval (CI). Data concerning procedures were evaluated by calculating weighted means across studies, a method that does not produce 95% confidence intervals.

Summary tables were produced for each outcome and treatment modality and were reviewed by the Panel. Additional summary tables stratified by whether stones were partial or complete and by age (adult versus pediatric) also were produced. In analyses stratified by patient age, estimates for pediatric patients were derived from studies or groups that contained only patients <18 years of age. Estimates for adults were from studies or groups that were not exclusively pediatric, including studies or groups with a mixture of pediatric and adult patients.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Treatment Guideline Statements

The present treatment guideline statements are graded with respect to three levels of flexibility: A "standard" has the least flexibility as a treatment policy; a "recommendation" has significantly more flexibility; and an "option" is even more flexible. These three levels of flexibility are defined as follows:

1. Standard: A guideline is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred;
2. Recommendation: A guideline is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable but not unanimous majority agrees on which intervention is preferred; and
3. Option: A guideline is an option if (1) the health outcomes of the alternative interventions are not sufficiently well known to permit meaningful decision, or (2) preferences are unknown or equivocal.

Index Patient

Standards, recommendations, and options for the treatment of patients with staghorn calculi apply to an "index patient." In this guideline, the index patient is defined as an adult with a staghorn stone (non-cystine, non-uric acid) who has two functioning kidneys (function of both kidneys is relatively equal) or a solitary kidney with normal function, and whose overall medical condition, body habitus,

and anatomy permit performance of any of the four accepted active treatment modalities, including the use of anesthesia.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft guideline report was reviewed and approved by all members of the Panel and was submitted for peer review to 61 reviewers of whom 35 provided comments. Based on peer assessment comments, the guideline was revised and forwarded to the Practice Guidelines Committee and the Board of Directors of the American Urological Association, both of which rendered approval.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse: The recommendations without the associated supporting text have been excerpted from the guideline. For full context, please refer to the original guideline document.

Definitions for the treatment guideline statements (standard, recommendation, and option) and "index patient" are given at the end of the "Major Recommendations" field.

Treatment Guidelines for the Index Patient

Standards

1. A newly diagnosed patient should be actively treated.
2. The patient must be informed about the relative benefits and risks associated with the active treatment modalities.

Recommendations

1. Percutaneous nephrolithotomy should be the first treatment utilized for most patients.
2. If combination therapy is undertaken, percutaneous nephroscopy should be the last procedure for most patients.
3. Shock-wave lithotripsy monotherapy should not be used for most patients; however, if it is undertaken adequate drainage of the treated renal unit should be established before treatment.

4. Open surgery (nephrolithotomy by any method) should not be used for most patients.

Options

1. Shock-wave lithotripsy monotherapy may be considered in patients with small-volume staghorn calculi with normal collecting-system anatomy.
2. Open surgery can be considered for patients in whom the stone is not expected to be removed by a reasonable number of less invasive procedures.

Recommendations for Non-index Patients

1. Nephrectomy should be considered when the involved kidney has negligible function.
2. Shock-wave lithotripsy monotherapy should not be used for patients with staghorn or partial staghorn cystine stones.

Option for Non-index Patients

1. Shock-wave lithotripsy monotherapy or percutaneous-based therapy may be considered for children.

Definitions:

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and anatomy permit performance of any of the four accepted active treatment modalities, including the use of anesthesia.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guidelines are generally based on current professional literature, clinical experience and expert opinion. The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

This guideline is intended to help both the clinician and the patient choose the most appropriate treatment modality.

POTENTIAL HARMS

Acute complications include transfusions, death, and overall significant complications. Death attributable to any of the four treatments is rare but can occur particularly in patients with medical comorbidities or in those who develop sepsis or other significant acute complications.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This report is intended to provide medical practitioners with a consensus of principles and strategies for the treatment of staghorn calculi. The report is based on current professional literature, clinical experience and expert opinion. It does not establish a fixed set of rules or define the legal standard of care and it does not pre-empt physician judgment in individual cases.
- Limitations to the process of developing the treatment guidelines became apparent during the Panel's review of the literature. Most obviously, there was no uniform system of categorizing staghorn calculi, no standard method of describing the collecting-system anatomy and no widely utilized system for reporting the size of staghorn calculi. Although the most valid data for a meta-analysis are generated by randomized, prospective studies, only one such study was available for this analysis, one more than for the previous guideline project. There also was limited published data on long-term treatment outcomes for this patient cohort, and the long-term data reported was not presented using a standardized system. Further uncertainty stems from differences in health care delivery systems in various countries that may impact the outcomes reported in the literature. Variability in the data leads to

uncertainty in outcome estimates, which leads to flexibility in guidelines, a limitation that applies to a variety of outcomes.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005

GUIDELINE DEVELOPER(S)

American Urological Association Education and Research, Inc. - Medical Specialty Society

SOURCE(S) OF FUNDING

American Urological Association Education and Research, Inc. (AUA)

GUIDELINE COMMITTEE

Nephrolithiasis Guideline Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Glenn M. Preminger, M.D., Chairman; Dean G. Assimos, M.D., Vice-chairman; James E. Lingeman, M.D.; Stephen Y. Nakada, M.D.; Margaret S. Pearle, M.D., Ph.D.; J. Stuart Wolf, Jr., M.D.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Funding of the committee was provided by the American Urological Association (AUA). Committee members received no remuneration for their work. Each member of the committee provided a conflict of interest disclosure to the American Urological Association.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Urological Association, Inc. (AUA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on April 21, 2005. The information was verified by the guideline developer on May 13, 2005.

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